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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/828,359 | 04/20/2004 | Tom Westberg | F-5495 DIV (9360-0172.01) | 4891 |
| 69275 7590 02/24/2009 COOK, ALEX, MCFARRON, MANZO, CUMMINGS & MEHLER, LT 200 WEST ADAMS STREET SUITE 2850 CHICAGO, IL 60606 | | | | |
| EXAMINER WIEST, PHILIP R | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/828,359

Applicant(s)

WESTBERG ET AL.

Examiner

Phil Wiest

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-850)
- Paper No(s)/Mail Date 11/18/08
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____
- 5) ☐ Notice of Inventor's Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

In the reply filed 11/18/08, applicant amended claims 1-3 and 6, and added new claims 7-18. Claims 1-18 are currently pending.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 2, 4, 5, 7, 10, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kamen et al. (5,350,357) in view of Lundback (US 4,647,877).

Kamen et al. (hereafter Kamen) discloses a medical fluid pumping device comprising a plurality of pumping stations (P1, P2), both of which comprising an inlet and an outlet, that operate by applying positive and negative pressures to a membrane. A controller applies pressure to the pumping stations in tandem, such that they synchronized to be alternately filled and emptied (Column 19-Lines 49-51). By operating in tandem, the pumps are capable of continuously receiving fluid and pumping it from a source to a destination. Regarding Claims 4, 5, 10, 11, 16, and 17, pneumatic fluid pressures are applied to the pumps and valves (Column 3, Lines 15-20). The controller operates the pumps in tandem such that the first pump is in a draw stroke while the second pump is in a pump stroke, and vice versa. By using this type of alternating, tandem pumping

method, it is ensured that a constant stream of fluid is being pumped into the inlet of the system, thereby improving the speed at which the device operates (Column 31, Line 58 through Column 33, Line 6). Kamen, however, does not specifically teach that the pumping system has a continuous fluid input and pulsatile fluid output.

Lundback discloses a pumping system and method that uses a pneumatic driving means to provide a pulsatile outflow and a continuous inflow. The system of Lundback comprises two pump stations, A and V, which are in communication between the fluid inlet and outlet (see FIG 3A). The method disclosed by Lundback includes a pumping stroke and a return stroke that operate in succession to one another in order to create a continuous inflow and a pulsatile outflow (see columns 6-7). This type of pump may be used in a variety of types of fluid systems, including blood pumping systems, in order to provide improved control over the flow rate of the fluid being pumped based on the pressure of the fluid source. Additionally, blood pumps of this type are well known in the art because they allow for fluid to be continuously received through the inlet, while producing a pulsatile outflow that resembles normal physiological flow (see Abstract). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to combine the blood processing system of Kamen with the pumping method of Lundback in order to provide a continuous inflow and pulsatile outflow, thereby providing a pressure-sensitive pumping system that mimics physiological blood flow.

Claim Rejections - 35 USC § 103

Claims 2, 3, 6, 8, 9, and 12-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kamen in view of Lundback, and further in view of Pages et al. (US 5,954,971). Kamen and Lundback reasonably suggest the device substantially as claimed, but do not specifically teach that the pumping system is used in conjunction with a blood processing apparatus for removing leukocytes. Pages et al. (hereafter Pages) discloses a blood processing system for removing leukocytes from blood comprising a plurality of blood inlets having flow control means (115v and 120v), a leukocyte filter 140, and a pump station 132, and a plurality of blood collection containers (145, 150) that receive blood from a separation device. The filter 140 communicates with blood collection containers (145, 150) that is located downstream of the filter. Although Pages teaches that a peristaltic pump is used to convey fluid through the system, any type of known medical pump may be used. Fluid-actuated pumps such as Kamen are well known in the medical art because they allow for continuous, precisely-controlled fluid flow. Therefore, it would have been obvious to use the fluid-actuated pumping system of Kamen to convey fluid through the blood processing system of Pages, in order to provide an alternate, more efficient means for filtering blood.

Response to Arguments

Applicant's arguments with respect to claims 1-18 have been considered but are moot in view of the new ground(s) of rejection. Applicant argues that Kamen, Pages, and Lundback do not teach or reasonably suggest the claimed device. This argument has not been found persuasive.

First, applicant argues that Kamen does not teach a fluid-actuated pumping system. This argument is moot because of the amendments to the claims.

Second, applicant argues that Kamen and Pages do not reasonably suggest a fluid processing system wherein pump stations are operated in tandem to convey fluid from a source to a destination. This has not been found persuasive because Kamen clearly teaches a fluid-activated pump station wherein the pump stations are controlled in tandem to create constant fluid flow. Additionally, just because Kamen teaches continuous flow at the inlets and outlets of the pumps does not mean that Kamen teaches away from pulsatile outflow. Kamen main focus is to alternately fill the pumping stations (i.e. provide continuous flow at the inlet) in order to prevent lags in fluid flow, and never explicitly states that pulsatile outflow is undesirable.

Third, applicant argues that pages does not teach a fluid pressure actuator that includes a control function to switch between a first mode and a second mode. This argument is moot because of the new grounds of rejection. Furthermore, Kamen clearly teaches a first pumping mode (wherein the first chamber is filled and the second chamber is emptied) and a second pumping mode (wherein the first chamber is emptied and the second chamber is filled). The controller alternates between these functions.

Fourth, in response to applicant's argument that there is no motivation to combine Kamen with Lundback, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). It would have been obvious to use the pulsatile outflow of Lundback in blood transfer systems to maintain physiological flow conditions.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phil Wiest whose telephone number is (571)272-3235. The examiner can normally be reached on 8:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Phil Wiest/
Examiner, Art Unit 3761

/Leslie R. Deak/
Primary Examiner, Art Unit 3761
29 January 2009